OU1 Risk Assessment Issues

Quantitative vs Qualitative Assessment	Response/Recommendation
Management (Carol R.) concern with performing a quantitative assessment for OU1: ○ Based on prior briefing, CR thought that the decision was made to perform only a qualitative assessment. ○ CR is concerned that a quantitative assessment at OU1 will imply to the public that one can be performed at OU4. ○ CR is concerned that quantitative assessment at OU1 sets precedence for the other OUs.	○ Exposure data are available for OU1. There is no basis for rejecting that data. Full tox team was not involved in the preparation or presentation of the prior briefing? ○ The risk assessment for OU4 (and other OUs) needs additional exposure information (background, low-activity exposures, and worker exposure pathways) before it can be completed. ○ Any risk assessment can be perceived as setting a precedent for the site, whatever form it takes. (e.g., vermiculite occurs in the subsurface at other OUs and the remedy applied at OU1 may be perceived as justified at other OUs). At any point in time when they are needed and exposure data are available, risk assessments are performed using the best available science.
Qualitative Assessment	**Response/Recommendation**
○ Tox team is concerned that the current draft of the qualitative risk assessment focuses only on the subsurface. ○ Tox team is concerned that the current draft of the qualitative risk assessment does not discuss non-cancer effects.	○ Tox team recommends adding a qualitative assessment of surface conditions. ○ Tox team recommends adding a qualitative assessment of non-cancer effects.

Quantitative Assessment (in general)	Response/Recommendation
Tox team disagrees on the emphasis RAGS places on quantitative assessment: o Wendy: RAGS A, Chapter 8, Section 8.1 ("Risk Characterization"), Exhibit 8-1, Page 8-3. Step 2 states: "Quantify Pathway Risks". From my perspective, this seems to succinctly sum up what the rest of the chapter recommends - quantitative risk assessment. The use of qualitative approaches is first broached later, in Section 8.4 ("Assessment and Presentation of Uncertainty", Page 8-17). o Paul: NCP refers to numerical departure points for cancer: evaluate risk range 1E-06 – 1E-04. o Bob: Considers Chapter 8 to provide great emphasis on the quantitative evaluation of risk and hazard. Qualitative assessment is discussed only in the sections on uncertainty analysis. o Chris: Believes RAGS does not strongly recommend quantitative risk assessment. Instead considers that RAGS leaves the risk assessor much latitude about how to perform a risk assessment.	

Quantitative Assessment (Cancer Risk)	Response/Recommendation
○ Paul: More data will not reduce variability or improve correlation between ABS data and Visible Vermiculite Score (VVS). Therefore, the risk assessment will need to rely on the correlation. ○ Kathryn: The correlation between OU4 ABS data and (VVS is statistically poor and should not be used to determine risks at OU1. Actual exposure data should be used. ○ Bob: VVS score is not an exposure point concentration and should not be used to perform a quantitative assessment. Actual exposure data should be used.	○ Use OU1-specific exposure concentrations to calculate risk.. ○ Use OU4 data as representative of range of concentrations in Libby. Use mean value of OU4 data and OU1-specific exposure parameters to calculate risks.
Quantitative Assessment (Non-Cancer Risk)	**Response/Recommendation**
○ Bob & Chris: The draft RfC value should be used to calculate non-cancer risk as it would be misleading to ignore the serious non-cancer risk from exposure to LA and possibly construed as withholding information. ○ Bob: Does not believe a qualitative discussion using ATSDR data is appropriate in a quantitative assessment since the ATSDR data has no quantitative basis. ○ Wendy: R8 has committed to follow a peer review process for the RfC. If we decide we are now not going to follow this process, there needs to be some communication with NCEA and OSWER as to why are not for OU1. One of the ramifications of proceeding with the draft RfC without communicating with NCEA/OSWER is potential blockage of the risk assessment for OU1. ○ A peer-reviewed value gives us and the community more confidence in the RfC we develop from the Marysville cohort. The value is important from the perspective that it may well drive the risk at Libby, and also that it will likely be used at other sites across the country. It is our responsibility as public servants to provide the most sound and defensible value possible. ○ RAGS A, Chapter 7, Section 7.5.3, Page 7-17, addresses derivation of tox values in the absence of EPA-derived tox values. "Any such derivation should be done in conjunction with the regional risk assessment contact, who will submit the derivation to EPA's Environmental Criteria and Assessment Office for approval." As guidance states any tox values we derive on our own needs to be reviewed, we should proceed with the review process we have already set up. ○ Other regions have produced risk assessments for asbestos without an RfC.	

Options:

1) Perform only qualitative risk assessment (including discussion of both cancer risk and non-cancer effects.
2) Perform quantitative risk assessment:
    a) Cancer risk:
        i) Based on VVS and OU4-VVS correlation.
        ii) Based on OU4 exposure data as well as OU1 exposure data
        iii) Based only on OU1 exposure data
    b) Non-cancer effects:
        i) Based on draft RfC
        ii) Qualitative discussion only based on ATSDR data
3) Perform some combination of the above